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AUG - 2 2011

510(k) Summary
for the
Mesa Spinal System, Keystone Rods

This safety and effectiveness summary for the Range Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :
Nancy Giezen
Manager Regulatory Affairs
751 Miller Drive SE, Suite F1
Leesburg, VA 20175
Telephone: 703-777-3155

Date Prepared: April 07, 2011

2. Tradename: Mesa Spinal System
Common Name: Spinal Fixation System
Classification Name: Orthosis, Spinal Pedicle Fixation (21 CFR 888.3070)

3. Predicate or legally marketed devices which are substantially equivalent :

- Mesa Spinal System (K2M, Inc.)
- Range Spinal System (K2M, Inc.)
- Easyspine (LDR Spine)

4. Description of the device :

The Mesa Spinal System is a top-loading, multiple component, spinal fixation system. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

Materials: The devices are manufactured from titanium and cobalt chrome per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of spinal segments of the thoracic, lumbar and / or sacral spine.

5. Intended Use:

The Range Spinal System is comprised of the DENALI, DENALI DEFORMITY, and MESA Spinal Systems and the ARI Anterior Vertebral Body Staples, all of which are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The Mesa Spinal System was mechanically tested and compared to the predicate systems and other currently marketed systems and performed equal to or better than these systems in ASTM testing to F1717. The design features and sizing of the components were also compared and the Range Spinal System was found to be substantially the same as these systems. It is manufactured from the same materials and is indicated for the same intended uses as these systems.
There are no significant differences between the Range Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in function, material, sizes, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

K2M, Inc.
% Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

AUG - 2 2011

Re: K110991
Trade/Device Name: Mesa Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI
Dated: July 08, 2011
Received: July 11, 2011

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name : Mesa Spinal System

Indications For Use :

The Rangè Spinal System is comprised of the DENALI, DENALI DEFORMITY, and MESA Spinal Systems and the ARI Anterior Vertebral Body Staples, all of which are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription use __X__ OR Over-the-counter use _____
(PER 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110991